K090706

Nucletron

NUCLETRON B.V.
Waardgelder 1 3905 TH Veenendaal
P.O.Box 930 3900 AX Veenendaal
The Netherlands
Phone +31 318 557133
Fax +31 318 550485

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

JUN 15 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

New Device Name:

Trade/Proprietary Name:	Oncentra Simulation 2.3
Common/Usual Name:	Simulator
Classification Name:	System, Simulation, Radiation Therapy
Classification:	21Cfr892.5840 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Simulix Evolution	k033470

Description:

Oncentra Simulation 2.3 is a revision of the image handling software of the Simulix Evolution. This software has been adapted such that images can be acquired and processed from an Image Intensifier such as used on the Nucletron Radiotherapy simulators Simulix MC, Simulix HP and Simulix HQ. This makes it a replacement for the predicate device DTI (k954055).

The PC based simulator workstation comes with functionality to support simulation procedures:

- Image acquisition

- Image display
- Image enhancement and multiple views
- Database and DICOM Import / Export functionality
- Simulator controls

The modification to the previously cleared device k033470 is:

- Added support for Image Intensifiers

The software runs on a PC on a Windows XP platform.

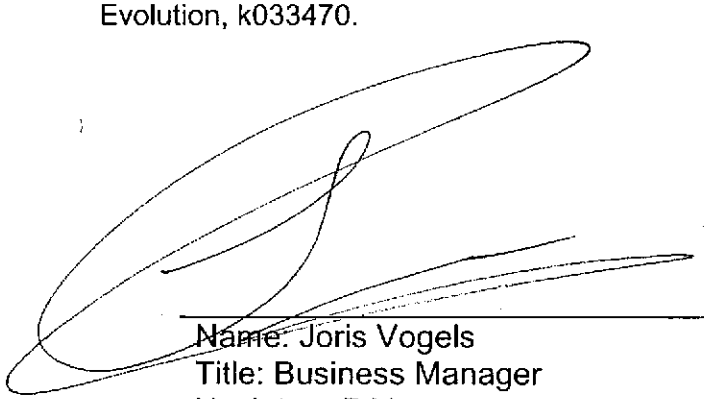
Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

Oncentra Simulation is an accessory to a radiation therapy simulation system which is intended to prepare patients for radiation therapy. The Simulator emulates the geometrical positions of radiation therapy treatment machines. Using conventional radiographic and fluorographic system, patients are positioned, filmed and marked to prepare them for treatment.

Summary of technological considerations:

Oncentra Simulation is substantially equivalent to the cleared predicate device, Simulix Evolution, k033470.



Name: Joris Vogels
Title: Business Manager
Nucletron B.V.
Veenendaal, The Netherlands

2-March-2009
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2009

Ms. Elaina M. Colby
RA/QA Manager
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046-2133

Re: K090706
Trade/Device Name: Oncentra Simulation
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: KPQ
Dated: May 8, 2009
Received: May 12, 2009

Dear Ms. Colby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

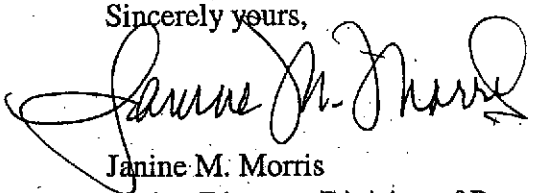
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K090706

Device Name: Oncentra Simulation

Indications for Use: Oncentra Simulation is an accessory to a radiation therapy simulation system which is intended to prepare patients for radiation therapy. The Simulator emulates the geometrical positions of radiation therapy treatment machines. Using conventional radiographic and fluorographic system, patients are positioned, filmed and marked to prepare them for treatment.

Prescription Use ___X___ (Part 21 CFR 801 subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090706